

CONFIDENTIAL

K032597

Page 5-1

NOV - 4 2003

Section 5

510 (k) SUMMARY

This summary of 510 (k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 190 and 21 CFR par 807.92

Trade Name: **BisCem GI**

Common Name: Luting cement

Classification/Name: Material, Dental Cement  
**Class II per 21 CFR 872.3275**

**Description of Application Device:**

**BisCem GI** is a dual-cured resin modified glass ionomer cement. It is a self-adhesion cement bonding to composite, metal, silanated porcelain and tooth structure without applying any adhesive. For bonding to dentin and enamel, no etching step is required. With its dual syringe system, **BisCem GI** can be self cured by simply mixing paste **A** and paste **B** or cured by light after mixing paste **A** and paste **B**. Using a mixing tip, the cement could be dispensed to the working area directly.

**Intended uses of Applicant Device:**

**BisCem GI** is a dual-cure radiopaque dental cement designed to be used as a luting cement. Its physical properties are similar to the predicate device and uses are identical.

**Predicate Device:** GC FujiCem

**Significant Performance Characteristics:**

	<b>BisCem GI</b>	<b>GC FUJICEM</b>
Intended use	Luting cement	Luting cement
Chemical composite	Dual-cured (light/self) dental glass filled, resin modified glass ionomer cement	Self-cured dental glass filled, resin modified glass ionomer cement
Mechanical/physical properties	Low viscosity, dispensable composite	Low viscosity, dispensable composite

Side by side comparisons of **BisCem GI** to the predicate device GC **FujiCem** clearly demonstrates that the applicant device is substantially equivalent to the legally marked devices. **BisCem GI** was tested for biocompatibility and it was found to be non-toxic. It is concluded that the information supplied in this submission has proven the safety and efficacy of **BisCem GI**.

Kathy Joung, Ph.D.  
Director of Quality Systems  
Telephone: 847-534-6106  
Fax: 847-534-6111



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**NOV - 4 2003**

Dr. Kathy Joung  
Director of Quality Systems  
Bisco, Incorporated  
1100 West Irving Park Road  
Schaumburg, Illinois 60193

Re: K032597  
Trade/Device Name: BisCem™ GI  
Regulation Number: 21 CFR 872.3275(b)  
Regulation Name: Dental Cement  
Regulatory Class: II  
Product Codes: EMA, KLE, and DYH  
Dated: August 21, 2003  
Received: August 29, 2003

Dear Dr. Joung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

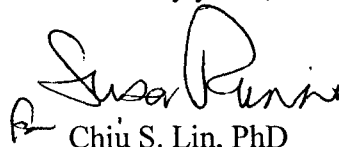
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Chiu S. Lin".

Chiu S. Lin, PhD

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

**CONFIDENTIAL**

Page 2-2

510 (k) Number (if known): K032597

Device Name: BisCem GI

Indications for Use:

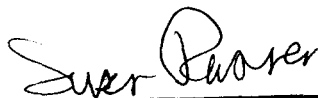
1. Luting metal crowns, bridges, inlay, and onlays including porcelain-fused-to-metal and composite-to-metal varieties;
2. Luting resin crowns, bridges, inlays, onlays and veneers;
3. Luting metal or non-metal posts;
4. Luting orthodontic appliances;
5. Luting porcelain inlays.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
IF NEEDED)

\_\_\_\_\_

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)



(Division Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

510(k) Number: K032597